IN THE DISTRICT COURT OF APPEAL FIRST DISTRICT, STATE OF FLORIDA

SHANDS TEACHING HOSPITAL AND CLINICS, INC., d/b/a SHANDS AT THE UNIVERSITY OF FLORIDA,

Case No. 1D22-1277 L.T. Case No. 2020-CA-819

Petitioner,

v.

KIMBERLY BEYLOTTE,

Resp	ond	ent.
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SHANDS TEACHING HOSPITAL AND CLINICS, INC., d/b/a SHANDS AT THE UNIVERSITY OF FLORIDA'S PETITION FOR WRIT OF CERTIORARI

Petitioner, Shands Teaching Hospital and Clinics, Inc., d/b/a Shands at the University of Florida ("Shands"), seeks review of the trial court's order compelling it to produce a document that it contends constitutes patient safety work product that is privileged and confidential under the Federal Patient Safety And Quality Improvement Act ("PSQIA"), 42 U.S.C. §§ 299b-21—299b-26.

BASIS FOR INVOKING THE COURT'S JURISDICTION

Defendants invoke the jurisdiction of this Court under article V, section 4(b)(3) of the Florida Constitution and Florida Rule of

Appellate Procedure 9.030(b)(2)(A).

Certiorari is appropriate when the trial court wrongly orders a party to disclose privileged and confidential information. *See Tarpon Springs Hosp. Found., Inc. v. White*, 286 So. 3d 879, 882 (Fla. 2d DCA 2019). Ordering discovery of privileged and confidential material is routinely recognized as establishing irreparable harm for the purpose of obtaining certiorari relief because once the information becomes public, its statutory protection has been lost forever. *See Progressive Am. Ins. Co. v. Herzoff*, 290 So. 3d 153, 156 (Fla. 2d DCA 2020) (acknowledging that discovery of "cat out of the bag" material "satisfies the jurisdictional requirements for certiorari relief").

NATURE OF RELIEF SOUGHT

Shands asks this Court to issue a writ of certiorari quashing the trial court's order compelling the production of a document that is privileged and confidential under PSQIA—a federal law that expressly provides that its privilege and confidentiality provisions cannot be waived. See 42 U.S.C. § 299b-22(d)(1).

The trial court's order also should be quashed because the court failed to conduct an in camera inspection prior to ordering the document to be produced. See Brinkmann v. Petro Welt Grading

Ges.m.b.H, 324 So. 3d 574, 578 (Fla. 2d DCA 2021) (trial court departs from essential requirements of law by ordering production of privileged information without first conducting an in camera inspection); Marshalls of M.A., Inc. v. Witter, 186 So. 3d 570, 572 (Fla. 3d DCA 2016) (same). Shands, nonetheless, submits that a remand solely for an in camera inspection would be futile and a waste of the resources of the judiciary and the parties. The trial court made clear its ruling was not based on the contents of the document, but instead on the title of the federal act, which as demonstrated below, was erroneous.

APPLICABLE LAW

This petition involves only the applicability of PSQIA. As the parties agreed below, it does not involve a record that was required by state law to be created and made discoverable by article X, section 25 of the Florida Constitution ("Amendment 7"). Consequently, the Florida Supreme Court's decision in *Charles v. Southern Baptist Hospital of Florida, Inc.*, 209 So. 3d 1199 (Fla. 2017)—which held that patient safety work product under PSQIA does not include records that state law independently requires hospitals to create and report to the state—has no applicability to this proceeding.

The parameters of PSQIA are set forth here to provide context for the remainder of the petition.

In 1999, the Institute of Medicine reported that many Americans die each year from preventable medical errors, most of which are not caused by isolated mistakes but by "system failures." S. Rep. No. 108-196, at 1 (2003). Explaining that "society's long-standing reliance on the threat of malpractice litigation discourages health care professionals and organizations from disclosing, sharing, and discussing information about medical errors," it recommended the creation of a protected system in which information might be shared and errors might be identified and evaluated without fear of blame and litigation. *Id.* at 1-2.

In response, Congress passed the PSQIA in 2005, codified at 42 U.S.C. § 299b-21, *et seq.* The purpose of the Act is to "facilitate an environment in which health care providers are able to discuss errors openly and learn from them." H.R. Rep. No. 109-197, at 9 (2005). The Act was intended to proactively replace a "culture of blame" with a "culture of safety" that emphasizes communication and cooperation. S. Rep. No. 108-196, at 2.

To that end, the Act creates a voluntary, confidential, non-

punitive system of data sharing of healthcare errors. 42 U.S.C. § 299b-22(a), (b). The term "patient safety activities"—the types of activities the Act is intended to capture—is broadly defined in PSQIA to include any of the following:

- (A) Efforts to improve patient safety and the quality of health care delivery.
- (B) The collection and analysis of patient safety work product.
- (C) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.
- (D) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.
- (E) The maintenance of procedures to preserve confidentiality with respect to patient safety work product.
- (F) The provision of appropriate security measures with respect to patient safety work product.
- (G) The utilization of qualified staff.
- (H) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

42 U.S.C. § 299b-21(5).

Healthcare providers who choose to participate in this federal

patient safety analysis and sharing system begin by establishing a patient safety evaluation system in which relevant information is collected, managed, and analyzed. *Id.* at § 299b-21(6). After information is collected for reporting in the patient safety evaluation system, the provider forwards it to a federally-approved patient safety organization. Patient safety organizations evaluate the information submitted by providers and provide "feedback and assistance to effectively minimize patient risk." *Id.* at § 299b-21(5)(D); *see also id.* at § 299b-24(b)(1)(G).

Information collected for submission to a patient safety organization is called "patient safety work product." The type of patient safety work product required by the trial court to be produced here was created under the "reporting pathway" authorized by the Act. It consists of "data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements," which "are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization," and which could result in improved patient safety, health care quality, or health care outcomes. *Id.* at § 299b-21(7)(A)(i).

Nothing in the definition of patient safety work product limits

such work product to information relating only to individuals who are admitted as patients to a hospital. Indeed, the definition provides that the privilege and confidentiality protections for patient safety work product apply to **all** reports assembled and developed by any licensed provider—including hospitals. *See* 42 U.S.C. § 299b-21(8).

Because the goal of PSQIA is to encourage providers to voluntarily report patient safety events, it provides "substantial and broad" protections to patient safety work product so providers can participate "without fear of liability or harm reputation." 73 Fed. Reg. 70,732-01, 70,741 (Nov. 21, 2008). These protections are "the foundation to furthering the goal of the statute to develop a national system for analyzing and learning from patient safety events." *Id.*

Consequently, PSQIA expressly provides that "[n]otwithstanding any other provision of Federal, state, or local law," patient safety work product shall be privileged, confidential, and not subject to disclosure. 42 U.S.C. § 299b-22(a), (b). In addition, providers who violate PSQIA by knowingly disclosing confidential patient safety work product are subject to mandatory penalties. *Id.* at § 299b-22(f)(1); *see also* 45 C.F.R. § 102.3 (updating penalty amount). Once the privilege and confidentiality protections attach,

the Act specifically states that they cannot be waived. See 42 U.S.C. § 299b-22(d)(1).

Not all information is patient safety work product deemed privileged under PSQIA. The privilege does not extend to (1) "a patient's medical record, billing and discharge information, or any other original patient or provider record," or (2) "information that is collected, maintained, or developed separately, or exists separately," from the provider's patient safety evaluation system. 42 U.S.C. § 299b-21(7)(B)(i), (ii). "Separate" information that is ultimately reported to a patient safety organization, but was not created for reporting to a patient safety organization, does not become protected patient safety work product. *Id.* at § 299b-21(7)(B)(ii).

FACTS UPON WHICH PETITIONER RELIES

Plaintiff sued Shands for injuries she allegedly sustained during a slip and fall on Shands' premises. (A.5). During discovery, Plaintiff requested "[c]opies of any investigative reports at or near the location of the slip and fall where the Plaintiff came into contact with the defendant's wall which reflects the substance near the wall where the Plaintiff contacted the Defendant's wall." (A.14).

Shands initially responded by making a general privilege

objection. (A.18). On September 3, 2021, Plaintiff moved to compel a response to request number 17. (A.20). Shortly thereafter, on September 17, 2021, Shands' counsel advised Plaintiff by letter of the steps it had taken to determine whether any "investigative reports" existed and how it came to the conclusion that none did. (A.26-27). Shands, however, further advised that, to the extent the request as phrased may involve patient safety work product, such work product is privileged and confidential under federal law and Shands is prohibited from disclosing it for any purpose. (A.27).

Plaintiff never scheduled her motion to compel for a hearing, and took no further action to obtain responses to her discovery. Discovery was thereafter closed on December 8, 2021 by court order, except that the parties were permitted to take the video depositions of witnesses previously disclosed who were not available for the new trial date. (A.29).

Plaintiff deposed Shands Nurse Manager Rose Phillips on February 17, 2022. (A.33). During her deposition, Nurse Phillips generally stated that if a person fell in her area of the hospital, she probably would have been the one to inspect the area to determine whether it was wet, and she would probably notify Shands' Risk

Management Department of the incident through a phone call. (A.37-38). She had no recollection of the specific events that occurred on the day Plaintiff fell. (A.39).

Plaintiff thereafter sent Shands a Request for Admissions, asking Shands to admit that it "did not create a Risk Management report documenting Plaintiff's fall as described in Plaintiff's Amended Complaint." (A.41). Shands admitted that no reports had been made pursuant to Florida's risk management statute regarding Plaintiff's fall. (A.43). Plaintiff later filed an amended motion to compel that included request for production 17. (A.45).

Shands responded to Plaintiff's amended motion to compel, explaining why the document is privileged and confidential under PSQIA. (A.53-54, 59-61). It also submitted an affidavit from its Director of Clinical Risk Management, Bradford Green, who attested that one document was created on October 30, 2017, within Shands' patient safety evaluation system; the document was created solely for submission to Shands' patient safety organization; and the document was submitted to Shands' patient safety organization. (A.68-69). Mr. Green also confirmed the report was not a medical record, billing or discharge information, or an original patient or provider record.

(A.69).

Shands further described the efforts it had undertaken in searching for documents responsive to Plaintiff's discovery requests, ensuring that it had not overlooked any type of "investigative report." Shands had already produced Plaintiff's medical record, which memorialized all of the information it had relating to Plaintiff's fall. (A.59-61).

At the hearing on Plaintiff's motion to compel, the court orally directed Shands to produce the document within five days, which would have been April 29, 2022. (A.98, 104). The court, however, did not enter its written order until May 4, 2022. (A.108).

The court's sole reasoning, without citation to any supporting statutory text or legal authority, was that PSQIA only applied to records involving patients and, consequently, could not apply to incidents reported to a hospital's patient safety organization concerning staff or patient visitors. (A.112-13).

The court did not find that Shands' privilege had been waived for failing to file a privilege log. (A. 108-13). It also did not review the

¹ Nor could the court make such a finding because, under the express terms of PSQIA, once the privilege and confidentiality protections

document in camera prior to ordering its production.

ARGUMENT

I. SHANDS IS IRREPARABLY HARMED BY THE TRIAL COURT'S ERRONEOUS ORDER.

Certiorari relief is appropriate from orders requiring discovery of privileged information because once such information is disclosed, there is no remedy on direct appeal for the production of privileged information. See Heartland Exp., Inc. of Iowa v. Torres, 90 So. 3d 365, 367 (Fla. 1st DCA 2012); see also Harborside Healthcare, LLC v. Jacobson, 222 So. 3d 612, 615 (Fla. 2d DCA 2019) (citations omitted).

As set forth below, the trial court's denial of Shands' privilege objection departs from the essential requirements of law and, once Shands is forced to disclose privileged information, there is no remedy on direct appeal. *Id.*

attach, they cannot be waived. See 42 U.S.C. § 299b-22(d)(1).

II. THE TRIAL COURT'S ORDER DEPARTS FROM THE ESSENTIAL REQUIREMENTS OF LAW.

Under the plain language of PSQIA, there are three requirements for information to constitute patient safety work product under the "reporting pathway":

- (1) The information must be developed for the purpose of reporting to a patient safety organization;
- (2) The information must have the ability to improve patient safety and the quality of health care; and
- (3) The information must be reported to the patient safety organization.

42 U.S.C. § 299b-21(7)(A)(i).

The record establishes that the document at issue fully satisfies these criteria: it was created pursuant to Shands' internal policies relating to its participation in and compliance with PSQIA, it was submitted to Shands' patient safety organization, and it was created to improve patient safety and the quality of healthcare.

The document also does not fall within any exception to patient safety work product because it does not encompass an original medical record, billing or discharge information, or any other patient record, and it was not collected, maintained, or developed separately from Shands' patient safety evaluation system. Nor was it created

pursuant to a separate reporting requirement of state law. The document is thus privileged and confidential as patient safety work product under the express provisions of PSQIA. Plaintiff presented no evidence disputing the accuracy of these representations to the trial court.

The trial court's conclusion—without any legal support—that PSQIA only applies to documents concerning admitted patients, and cannot extend to visitor patient safety events, is incorrect. First, nothing in the plain and unambiguous language of PSQIA limits its scope to reports that involve admitted patients, nor does it apply only to the delivery of medical care. *See generally* 42 U.S.C. §§ 299b-21 – 299b-26.

Moreover, any such limitation is contrary to the purpose of the Act, which is to, among other things, capture "near-misses" that occur in a hospital, including events involving the safety of visitors to a healthcare facility. The same conditions that jeopardize visitors in a hospital represent conditions that also adversely threaten a patient seeking care or being cared for in a hospital.

Indeed, healthcare providers are encouraged to develop "best practices" for the collection and protection of patient safety work

product so that any "near-miss" or safety event can be shared nationally with similarly-situated providers. 76 Fed. Reg. at 70,789.

Consequently, healthcare providers participating in PSQIA have developed robust systems or approaches to ensure that they capture any event that could involve patient safety, which necessarily encompasses any occurrence—including a premises defect—that could produce an injury if left uncorrected. This makes sense because it would be difficult (and incomplete) to create an organization-wide initiative that excludes staff and visitors. Further, many activities taken to improve patient safety (e.g., security, equipment safety, infection control) encompass staff and visitors as well as patients.

The breadth of information sought to be captured by PSQIA is also confirmed by "best practices" adopted among industry organizations, including the Alliance for Quality Improvement and Patient Safety, which is the leading national nonprofit professional association that assists its members in building safer health care systems. Consistent with the plain language of PSQIA, the Alliance defines a patient safety or quality related event as one that has harmed, or could have harmed, "a patient, healthcare provider **or**

visitor, whether or not a patient, healthcare provider or visitor is physically present." https://www.aqips.org/resources (last visited May 25, 2022) (emphasis added).

This is consistent with the broad patient safety activities providers are directed to capture under PSQIA and allows healthcare providers, such as Shands, to obtain information beyond what is required by state law, not only on incidents involving a serious injury but also on "near miss[es]," that it may analyze and use to prevent future actual injury.

RELIEF REQUESTED

The trial court's order should be quashed because it improperly compels Shands to produce a record that is privileged and confidential under federal law.

Respectfully submitted,

<u>/s/ Christine R. Davis</u>

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on June 1, 2022, a true and correct copy of the foregoing was filed with the Florida Courts E-Portal, electronically served on the following counsel of record through that portal, and served by email to the following trial judge who entered the order on review.

Trial Court Judge:

The Honorable Gloria R. Walker Alachua County Family & Civil Justice Center 201 East University Ave., Room 408 Gainesville, FL 32601 callowayc@circuit8.org

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<u>/s/ Christine R. Davis</u>

CERTIFICATE OF COMPLIANCE

I HEREBY FURTHER CERTIFY that the foregoing complies with the font and typeface requirements set forth in Florida Rule of Appellate Procedure 9.045 and complies with the word count limit requirements set forth in 9.100(g) because it does not exceed 13,000 words.

/s/ Christine R. Davis
Attorney